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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,307	09/18/2003	Bassil I. Dahiyat	067461-5041-US06	6927

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EXAMINER

DEJONG, ERIC S

ART UNIT PAPER NUMBER

1631

MAIL DATE DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No. 10/665,307	Applicant(s) DAHIYAT ET AL.	
Examiner Eric S. DeJong	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 July 2007.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 7-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 7-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED OFFICE ACTION

Applicants response filed 07/19/2007 is acknowledged.

Claim 6 has been canceled. Claims 1-5 and 7-26 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 and 7-26 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The instant claims are drawn to a method of generating a second library of protein sequences comprising utilizing input coordinates of a target protein to generate a primary library of protein sequences comprising variant amino acid positions, generating a probability distribution of said plurality of variant positions, generating a second library of sequences based on said probability distribution and synthesizing a plurality of said secondary sequences. Further recited embodiments a target protein that is an enzyme or therapeutic protein, and primary variant positions comprising regions surrounding a binding site, active site or catalytic site.

However, the instant claims do not recite any particular improvement or resultant characteristic that is imparted to proteins generated by the instant method or how

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analysis of the resultant secondary protein sequences would be used to yield any useful information. The Court of Patent and Appeals has stated:

"Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." A 'use' to do further research is not considered a utility which provides an "immediate benefit" to the public.

Examples of situations requiring further research to identify or reasonably confirm a "real world" context of use, and which do not have utility under 35 USC 101, as set forth in MPEP 2107.01.1, include:

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved, and

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility.

The instant claims encompass a process of basic research drawn to studying properties (sequence variation) of a protein structure and as such do not result in an "immediate benefit" to the public. As noted in the utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility (see page 6 of the Utility guideline training materials). Therefore, the instant claims do not have a substantial utility.

Claims 1-5 and 7-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

The rejection of claims 1-5 and 7-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-8 of U.S. Patent No. 6,403,312 is withdrawn in view of applicants filing of the terminal disclaimer set forth on 07/09/2007.

The provision rejection of claims 1-5 and 7-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-41 of copending Application No. 09/782,004 and over claims 52-69 of copending Application No. 09/927,790 is withdrawn in view of applicants filing of the terminal disclaimer set forth on 07/09/2007.

Conclusion

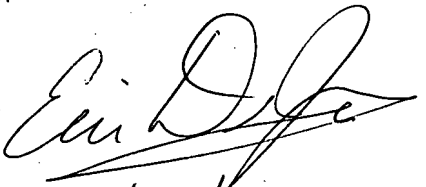
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
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09/29/2007